



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/582,868

04/25/2007

Jean-Louis Viovy

121697

5953

25944 7590 05/08/2009

OLIFF & BERRIDGE, PLC
P.O. BOX 320850
ALEXANDRIA, VA 22320-4850

EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

05/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,868	VIOVY ET AL.	
	Examiner	Art Unit	
	Ethan Whisenant	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 30-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 JUN 06 and 14 OCT 08 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

NON-FINAL ACTION

1. The applicant's after final response (filed 31 MAR 09) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 1-28 and 30-35** is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application. **The finality of the previous Office action is hereby withdrawn in order to make a new grounds of rejection.**

35 USC § 112 - 1ST PARAGRAPH

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

CLAIM REJECTIONS under 35 USC § 112- 1ST PARAGRAPH

3. **Claim 25** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

In making a written description rejection examiners has been advised to follow guidelines during their analysis which guidelines include at least five stages. ¹To begin, the examiner is to determine what each claim as a whole covers. Here the examiner is to determine and consider the full scope of the claim. ²Next the examiner is to fully review the application to understand how the applicant provides support for the claimed invention including each element and/or step. This review should include a comparison of the claim scope and the scope of the description. ³Then, the examiner is to

Art Unit: 1634

determine whether one skilled in the art would recognize that the applicant was in possession of the claimed invention as a whole at the time of filing. It has been recommended that Stage 3 should include the following considerations: ^aactual reduction to practice ; ^bthe disclosure present in the drawings and/or chemical formulas; ^care sufficient relevant identifying characteristics present (e.g. complete structure, partial structure, physical and/or chemical properties, functional characteristics) ; ^dmethod of making the claimed invention , ^ethe level of skill in the art , ^f the predictability in the art. ⁴Finally , the examiner, if considering a claim drawn to several embodiments or a genus, should determine whether one of ordinary skill in the art would recognize that applicant was in possession of a representative number of species which would lead one to conclude that the applicant was in possession of the claimed invention.

As for the written description rejection, applicant must describe the invention in sufficient detail so as to reasonably suggest that they were in possession of the invention at the time of filing. Applicant has not identified the probes/primer/target nucleotide sequences such that the method could be practiced. Seemingly applicant is, by inference, asserting that the probes/primer/target sequences are all known and are within the knowledge of the ordinary artisan. Such is an improper shifting of the burden of applicant providing an adequate written description of the invention. Assuming *arguendo*, that certain genes were known, what mismatch is to be equated with a certain diagnosis, prognosis and/or predisposition.

Applicant's attention is directed to *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1433:

Plaintiff also argues that the requirements for written descriptions of claims to chemical compounds are irrelevant to this case because the '850 patent does not claim a compound, but a method of treatment by targeting PGHS-2 activity over PGHS-1 activity. Virtually any compound claim could be transformed into a method claim, however, simply by means of wording the claim in terms of a method of using the compound. With respect to the issue before the Court, then, this is little more than a semantic distinction without a difference. The claimed method depends upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed

Art Unit: 1634

method of treatment. It means little to "invent" a method if one does not have possession of a substance that is essential to practicing that method. Without that substance, the claimed invention is more theoretical than real; it is, as defendants argue, akin to "inventing" a cure for cancer by utilizing a substance that attacks and destroys cancer cells while leaving healthy cells alone. Without possession of such a substance, such a "cure" is illusory, and there is no meaningful possession of the method.

What the inventors did not do, however, is succeed in taking the last, critical step of actually isolating such a compound, or at least of developing a process through which one skilled in the art would be directly led to such a compound. Absent that step, their discoveries, valuable though they might have been, did not blossom into a full-fledged, complete invention. Scientific discoveries, and theories based on those discoveries, frequently lay the groundwork for later inventions, but that does not make the discoverer the inventor as well.

While the case at hand is not directed to finding a compound, the claimed method requires one to use any number and combinations of compounds so to arrive at an infinite number of diagnoses, prognoses etc., wherein the afflicted organism can be virtually any life form- plant or animal. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

4. Claim(s) 25 is/are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting a point mutation using heteroduplex analysis, does not reasonably provide enablement for the entire scope of a method of diagnosing a predisposition to genetic diseases or cancers associated or putatively associated to specific point mutations. The specification does not enable any

Art Unit: 1634

person skilled in the art to which it pertains, or with which it is most nearly connected to make the invention commensurate in scope with these claims without undue experimentation.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, the breadth of the claim encompasses a method of diagnosing a predisposition to genetic diseases or cancers associated or putatively associated to specific point mutations in any and all living organisms. Furthermore, the claim encompasses the detection of any mutation associated with any cancer or any genetic disease - even those not yet discovered. For purposes of examination, the examiner has construed "disease" or "cancer" to include those which would afflict any animal and/or any plant.

As to the presence or absence of working examples, a review of the specification finds eight examples: Example 1, p. 32; Example 2, pp. 32-33; Example 3, pp. 33-34; Example 4, pp. 34-35; Example 5, pp. 35-36; Example 6, p. 36; Example 7, pp. 36-37; and Example 8, p. 37. While there is no *per se* rule that an applicant provide any examples, real or prophetic, applicant still must enable the fully scope of the claims. None of the examples are directed to either a) a method of diagnosing predisposition to any disease; b) a method of diagnosing a predisposition to any cancer; c) a method of diagnosing any disease; d) a method of diagnosing any cancer; e) a method of determining the prognosis of any disease; or f) a method of determining the prognosis for any cancer in any life form. While applicant is not required to teach each and every possible embodiment of the claimed invention, they do need to fully

Art Unit: 1634

enable the scope of the claims. Such has not happened here. Clearly, applicant must set forth the reaction conditions and starting materials needed to practice the invention. See *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

“ [T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.’ *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) (‘[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.’).

“Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that ‘a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.’) Tossing out the mere germ of an idea does not constitute an enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

“It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate

Art Unit: 1634

enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

A review of the disclosure finds Table 1 (p. 31) providing sequences that are tied to specific exons of BRCA1 and BRCA2. The specification does not develop how these exons are to be tied to any specific cancer, disease, predisposition, or prognosis. While BRCA1 and BRCA2 have been tied in the art to breast cancer, it is noted that applicant is not claiming a method in a Jepson format. Given that this is not a Jepson-format claim, there is no assertion by applicant as to what is known in the art.

At page 20, bridging to page 21, of the specification, applicant lists certain genes and related disease. The specification does not teach the nucleotide sequence of these genes or incorporates by reference the nucleotide sequence as found in a journal or database. Also, applicant does not identify where the mismatches are, much less what probes/primers are to be used. Even if this info was present, what prognosis is one to be making for a given individual? How does age (infant v. adolescent v. adult v. geriatric), gender, prior medical conditions/treatments (e.g., pregnancy, immunosuppression therapy, diabetes, etc.) impact on an accurate and reproducible diagnosis of a predisposition to a given genetic disease or cancer associated or putatively associated to specific point mutation(s) or the diagnosis or prognosis of said diseases or cancers.”

35 USC § 112- 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

6. Claim(s) 12-13 and 25 is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is confusing in light of the limitation which reads “the oligonucleotide(s) or nucleoside(s) in the mixture of oligonucleotides or nucleosides are unable to undergo mutually base pairing interaction” in light of the limitation in Claim 1 which requires that the compound be able to undergo a specific base pairing interaction with said mismatch. Please clarify what is intended.

Claim 25 is indefinite because the phrase “said duplex ” on line 4, lacks proper antecedent basis.

35 USC § 102

7 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

CLAIM REJECTIONS UNDER 35 USC § 102

8. Claim(s) 32 and 34-35 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Saiki et al. [Nature 324 : 163-166 (1986)].

Saiki et al. teach a composition [i.e. their PCR reaction mixture(s)] including at least a compound (i.e. the dNTPs present at a concentration of 1.5mM each) which compound is able to undergo specific base pairing interaction at a concentration of at least 1g/L. At 1.5mM of each dNTP the concentration of the dNTPs in the Saiki et al reaction mixture(s) is approximately 3.347g /L (i.e. at least 1g/L). See especially the legend of Figure 2.

9. Claim(s) 27-28, 31-33 is/are rejected under 35 U.S.C. 102(a) as being anticipated by Fisher BioReagents exACTGene PCR Kits [copyrighted (2003)].

Fisher BioReagents Advertisement for the exACTGene PCR kit teach a composition (i.e. kit) including at least a compound (i.e. the nucleotide mix comprising 10mM of each nucleotide) which are compounds able to undergo specific base pairing interaction at a concentration of at least 1g/L. At 10 mM of each dNTP the concentration of the dNTPs in the PCR nucleotide mix is approximately 5g /L of each dNTP or a total concentration of all dNTPs of approximately 20g/l (i.e. at least 1g/L). As regards the liquid separating medium, this is equivalent to the buffer in which the dNTPs are dissolved.

35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 103

12. **Claim(s) 1-4, 6-10, 14-18 and 25-26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Fishel et al. [WO99/10369 (1999)].

Fishel et al teach a method for assaying for the presence or absence of at least one mutation on a strand of nucleic acids paired in duplex form which comprises all of the limitation recited in Claim 1 except these authors do not teach an embodiment in which a compound(s) able to undergo specific base pairing interaction with the mismatched nucleotide(s) is used at concentration of at least 10g/L. Rather, Fishel et al. teach using such compound (i.e. poly dI-dC) at only 10ng/μl which is equivalent to 10mg/L. See the paragraph bridging pages 58-59 A review of the specification found applicant speaking of preferred ranges, however, the range recited is not specific, but encompasses any and all values above a certain threshold. Such a broad range speaks to routine optimization not an unexpected result.

It is well settled that routine optimization is not patentable, even if it results in of proving such criticality. See *In re Swenson et al.*, 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; *In re Scherl*, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. *In re Sola*, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; *In re Normann et al.*, 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66

Art Unit: 1634

USPQ 308; *In re Irmischer*, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Swain et al.*, 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; *Minnesota Mining and Mfg. Co. v. Coe*, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; *Allen et al. v. Coe*, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136. (Emphasis added)

13. Claim(s) 19-24 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Fishel et al. [WO99/10369 (1999)].as applied to Claim 19 above and further in view of Righetti et al. (1997-cited by applicant) and/or Viovy et al. [Current Opinion in Biotechnology 14 : 51-57 (2003)].

Claim 19 is drawn to an embodiment of the method of Claim 1 wherein said mutation is assayed by electrophoretic analysis using a liquid separating medium.

Fishel et al. reasonably suggest a method for assaying for the presence or absence of at least one mutation on a strand of nucleic acids paired in duplex form which comprises all of the limitation recited in Claim 19 for the reason(s) outlined above against Claim 1 except Fishel et al. do not teach performing the electrophoretic analysis using a liquid separating medium. Rather, these authors teach analyzing their heteroduplex strands via polyacrylamide gel electrophoresis. However, as evidenced by both Righetti et al. and/or Viovy et al. the use of liquid separating media in electrophoretic analyses of DNA was known prior to the instant invention. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Fishel et al. wherein a liquid separating medium as taught by Righetti et al. and/or Viovy et al. is used in place of the polyacrylamide gel format used by Fishel et al.

14. Claim(s) 30 is/are rejected under 35 U.S.C. 102(a) as being anticipated by Fisher BioReagents Advertisement for exACTGene PCR Kits [copyrighted (2003)] in view of Righetti et al. (1997-cited by the applicant).

Fisher BioReagents Advertisement teach a composition (i.e. kit) including at least a compound (i.e. the nucleotide mix comprising 10mM of each nucleotide) which are compounds able to undergo specific base pairing interaction at a concentration of at least 1g/L. Fisher BioReagents Advertisement does not teach including in the kit a sieving polymer, however, it routine in the art to include in kits any and all of the reagents necessary to carry out a particular assay. Righetti et al. teach capillary electrophoresis of PCR products/ heteroduplex analysis using a liquid separating medium comprising a sieving polymer, see pp. 262-267. Given that a composition (i.e. a kit) for amplifying a target nucleic acid was known and given that the analysis of a PCR amplification product via electrophoretic analysis was routine in the art, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result to include in the exACTGene kit any reagent necessary to carry out the PCR methodology including a liquid separating medium comprising a sieving polymer as taught by Righetti et al. The ordinary artisan would have been motivated to make this modification in order to allow the end user to practice the PCR methodology without having purchase and prepare all of the reagents necessary to practice the method without having purchase each of the reagents separately which would afford to the end user convenience, ease of use and a cost savings.

15. Claim(s) 1-2, 5, 8-11 and 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pastinen et al. [Genome Research 7 :606-614 (1997)].

Pastinen et al teach a method for assaying for the presence or absence of at least one mutation on a strand of nucleic acids paired in duplex form which comprises all of the limitation recited in Claim 1 except these authors do not teach an embodiment in which a compound(s) able to undergo specific base pairing interaction with the

Art Unit: 1634

mismatched nucleotide(s) is used at concentration of at least 10g/L or 1g/L. Rather, Pastinen et al. teach using such compound(s) (i.e. the dNTPs) at only 0.2 pmol in 14.5 µl which is equivalent to a concentration of approximately 4pg / L of dNTPs. See the description of the minisequencing reactions which begins on p.611 and ends on p.613. A review of the specification found applicant speaking of preferred ranges, however, the range recited is not specific, but encompasses any and all values above a certain threshold. Such a broad range speaks to routine optimization not an unexpected result.

It is well settled that routine optimization is not patentable, even if it results end up proving criticality. See *In re Swenson et al.*, 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; *In re Scherl*, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. *In re Sola*, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; *In re Normann et al.*, 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; *In re Irmscher*, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Swain et al.*, 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; *Minnesota Mining and Mfg. Co. v. Coe*, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; *Allen et al. v. Coe*, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136. (Emphasis added)

CONCLUSION

16. Claim(s) 1-28 and 30-35 is/are rejected and/or objected to for the reason(s) set forth above.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by

Art Unit: 1634

telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz, can be reached at (571) 272-0763.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/
Primary Examiner
Art Unit 1634

EXAMINER SEARCH NOTES

31 APR 09 - ECW

Databases searched: USPATFULL, USPG-PUBS, JAPIO and EUROPATFULL via EAST &

CAplus, Medline and BIOSIS via STN

Reviewed the parent(s), if any, and any search(es) performed therein : see the BIB data sheet

Reviewed, the search(es), if any, performed by prior examiners

Search terms:

Inventor(s) : e.g. Viovy J?/au

Hybridiz\$

competit\$

dNTP\$ or dATP\$ or dGTP\$ or dCTP\$ or dTTP\$

NTP\$ or ATP\$ or GTP\$ or CTP\$ or UTP\$

array\$ or microarray\$ or solid support\$ or bead\$ or particle\$

PCR

Chain extension

Liquid separating medium

Acrylamide\$ or polymer\$ or copolymer\$

EHDA or Electrophoretic Heteroduplex Analysis

Heteroduplex Analysis